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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,913	08/21/2003	Herbert Peter Jennissen	034258-1401	8136
30542	7590	02/09/2006	EXAMINER	
FOLEY & LARDNER LLP			NAFF, DAVID M	
P.O. BOX 80278			ART UNIT	
SAN DIEGO, CA 92138-0278			PAPER NUMBER	
			1651	
DATE MAILED: 02/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/646,913

Applicant(s)

JENNISSEN, HERBERT PETER

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/554,972.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/27/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

A preliminary amendment of 8/21/03 amended the specification, canceled claims 1-14 and added new claims 15-31. A preliminary amendment of 3/22/04 canceled claims 1-31, and added new claims 32-44.

5        Claims examined on the merits are 32-44, which are all claims in the application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.

112:

10        The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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      Claims 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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      The specification fails to disclose a spacer molecule functioning to reduce nonspecific binding as in claim 39 and agarose function as a spacer as in claim 40. There is only disclosure of agarose reducing nonspecific binding when bound to the anchor molecule. Other materials are disclosed as being a spacer, which are not described as reducing nonspecific binding.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C.

112:

5       The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-37 and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out  
10 and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 and claims dependent thereon are indefinite by claim 35 in the last two lines being unclear as to materials that are the bone growth factor. It is unclear as to whether ubiquitin and an  
15 antibiotic are to be the growth factor. These materials are not normally bone growth factors. It is suggested that ubiquitin and an antibiotic be listed as the first two members of the Markush group, and a bone growth factor as the last member. Additionally, reciting "selected from the group consisting of a bone growth factor from the  
20 class of the BMP proteins" is an improper Markush group since such a group should recite distinct members rather than lump all of the members together as a class.

Claims 41-44 are unclear by claims 41 and 43 requiring an implant produced by the method of claim 32 or 35 since claims 32 and 35 are  
25 immobilizing a mediator molecule on an implant material rather than producing an implant material. Claims 41 and 43 should read --- An

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implant material containing an immobilized mediator molecule produced by the method of claim \_\_\_\_ ---.

Claim 42 is unclear as to which member of the Markush group of implant materials of claim 32 contains each member of the implant materials in the Markush group of claim 42.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15 Claims 32-37 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sukenikk et al (WO 92/00047) in view of Vosika et al (WO 90/09798) taken with Senter et al (5,306,307) or Mueller et al (5,837,235) (all listed on 1449).

The claims are drawn to attaching mediator molecules to an implant material by covalently bonding anchor groups having functional groups and then attaching mediator molecules to the functional groups.

25 The mediator molecules can be BMP, an ubiquitin or an antibiotic, and the implant material can comprise a metal, a metallic alloy or a ceramic material. In claim 38, a spacer is bound to the anchor molecule, and the mediator molecule is bound to the spacer.

Sukenikk et al disclose attaching a monolayer having functional groups to an implant surface and then coating with an adhesion

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mediating molecule. The surface may be oxidized and contain oxide groups (Figs 1 and 5, and page 29, lines 13-26).

Vosika et al disclose coupling cytokines to a support having functional groups by attaching a linking arm to the functional groups and then attaching a cytokine to the linking arm (paragraph bridging pages 23 and 24, and page 24, lines 8-29).

Senter et al (paragraph bridging cols 3 and 4) and Mueller et al (col 3, lines 32-49) disclose a metal implant containing BMP to promote bone formation.

It would have been obvious to attach the mediator molecule of Sukenikk et al using a linking arm as suggested by Vosika et al since this would have been expected to provide an effective way of attaching the mediator molecule by covalent bonding. The linking arm is inherently an anchor molecule. It would have been further obvious to use the linking arm to attach BMP as suggested by Senter et al or Mueller et al when desiring to obtain the function of BMP to promote bone formation. The limitations of dependent claims would have been matters of obvious choice in view of the disclosures of the references.

***Claim Rejections - 35 USC § 103***

Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 32-37 and 41-44 above, and further in view of Matsumoto et al (4,371,612).

The claim requires a spacer molecule to be bound to the anchor molecule and the mediator molecule to be bound to the spacer. The spacer can reduce nonspecific binding.

Matsumoto et al disclose direct bonding or using a spacer when  
5 binding a biological material to a polymer (col 5, lines 55-57).

When modifying Sukenikk et al as set forth above, it would have been obvious to use a spacer as suggested by Matsumoto et al to obtain space between the carrier and material immobilized. The spacer would inherently reduce nonspecific binding as in claim 39.

10 ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated  
15 by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164  
20 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the  
25 conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the  
35 assignee must fully comply with 37 CFR 3.73(b).

Claims 32-37 and 41-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,635,269 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed method of immobilizing a mediator molecule on an implant encompasses the method of the patent claims of immobilizing a mediator molecule on an implant.

#### ***Double Patenting***

Claims 38 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,635,269 B1 as set forth above, and in view of Matsumoto et al. Matsumoto et al would have suggested the use of a spacer in the claims of the patent for the reason set forth above when applying Matsumoto et al.

#### ***Conclusion***

Claim 40 is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN

2/6/06